

**FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)**

***Nonprescription Drugs Advisory Committee Meeting
October 20, 2005***

Committee Questions

1. As drug products, should consumer antiseptics be expected to provide clinical benefit by reducing infection risk? (vote)

2. Based on the information in the background materials and today's presentations, are there any populations, outside of the healthcare setting, in which consumer antiseptic use has been demonstrated to be more effective than use of plain soap in reducing infection rates? (vote)

If yes, please describe the population and the category of consumer antiseptic that provided benefit (e.g., antiseptic handwash, antiseptic bodywash, hand sanitizer).

If no, what criteria should be used to define a consumer population for which washing with plain soap and water, or other hygiene measures that do not involve antiseptic drug products, are inadequate to reduce infection risk?

3. Earlier this year, NDAC met to discuss the efficacy criteria for healthcare antiseptic drug products and accepted clinical simulation testing as a surrogate for bacterial infection rate to measure efficacy of healthcare antiseptics. What type of studies/endpoints should be used to establish efficacy in populations that require consumer antiseptics?

4. As with many drugs, the use of consumer antiseptics may be associated with a number of adverse consequences. The extent to which these consequences are attributable to consumer antiseptics, and the importance of the consequences to public health, are varied. How should each of the following be factored into FDA's decisions about product regulation?
 - a. Application site consequences for the individual user (e.g., local irritation, dryness).
 - b. Systemic consequences for the individual user (e.g., incomplete immune system development, development of antibacterial resistance in the individual).
 - c. Societal consequences associated with chronic exposure of the environment to consumer antiseptics (e.g., widespread development of antibacterial resistance, antiseptic impact on ecosystems, secondary exposure to humans).